

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SCIELE PHARMA, INC. and SCIELE
PHARMA CAYMAN LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC. and
MYLAN LABORATORIES, INC.,

Defendants.

)
) Civil Action No. 07-cv-00664 (GMS)
)
) **PUBLIC VERSION**
)
)
)
)
) ORAL ARGUMENT REQUESTED
)
)
)

**REPLY MEMORANDUM IN SUPPORT OF DEFENDANT MYLAN'S RULE
12(b)(1) MOTION TO DISMISS PLAINTIFF SCIELE'S COMPLAINT FOR
LACK OF STANDING AND SUBJECT MATTER JURISDICTION**

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Mylan respectfully submits this reply in support of its motion to dismiss Sciele's Complaint for lack of standing and subject matter jurisdiction.

INTRODUCTION

Nothing Sciele has said, or could say, changes the fact that Sciele neither owns, nor holds *all* substantial rights, in the '741 patent, and thus lacks standing to bring this suit. With no sense of irony, Sciele accuses Mylan of "jump[ing] the gun" with this motion. But in fact, just the opposite is true—Sciele jumped the gun by filing this premature suit in its own name even though it lacks standing to do so. By jumping the gun, Sciele obtained a 30-month stay of FDA approval of Mylan's competing generic product to which it is not entitled. The Court, therefore, should dismiss this suit for lack of standing and subject matter jurisdiction. The Court should also deny Sciele's request for leave to file an amended complaint, because doing so would only condone Sciele's premature filing and subject Mylan to enormous prejudice, including an unwarranted 30-month stay. If Sciele still wishes to file suit, it can do so properly by filing a new suit with Bayer.

Sciele concedes that it does not now own—and indeed has never owned or otherwise held legal title to—the '741 patent, which is owned solely and exclusively by Bayer, which has not filed suit. Sciele further concedes that it only required "certain [and not all substantial] rights" in the '741 patent under the original 2001 Distributorship Agreement ("the 2001 Agreement"), and does not even attempt to argue otherwise. And nor could it, since Bayer retained substantial rights in the '741 patent, including: sole and exclusive ownership; the right and obligation to enforce the patent in the first instance; the right and obligation to maintain the patent and seek extensions thereof; and exclusive manufacturing rights under the patent. In short, as Sciele concedes, nothing in the 2001 Agreement confers standing to sue.

To justify standing to bring this premature suit, Sciele now points to a “New Distributorship Agreement,” dated October 1, 2004 (“the 2004 Agreement”)—which was not available or provided to Mylan until Sciele’s response—that purportedly supersedes relevant parts of the 2001 Agreement. But the 2004 Agreement, to the extent it supersedes anything, fares no better. In fact, as the parties intended,

REDACTED

Nothing in the 2004 Agreement changed or otherwise enlarged Sciele’s rights in the patent, and certainly not in any fashion that would confer standing to sue in its own name without Bayer.

Realizing and acknowledging this problem,

REDACTED

But whatever that Amendment did, it did not transfer *all* substantial rights in the patent to Sciele.

REDACTED

If, as Sciele contends, the intent of the parties must govern, the intent from all of the agreements is clear: Bayer admittedly could have, but did not, transfer all substantial rights in the patent to Sciele, but rather retained substantial rights for itself, including the right to sue Mylan and others. No more is required for dismissal of this suit for lack of standing and subject matter jurisdiction.

I. Sciele Lacks Standing To Sue As The Patentee Because Admittedly It Does Not Hold Legal Title To The ‘741 Patent.

As an initial matter, Sciele concedes, as it must, that it is not the record owner or

assignee of, and does not hold actual legal title to, the '741 patent. (*See* Sciele Mem. at 4).¹ Rather, Bayer remains the “sole and exclusive owner of the ['741 patent],” as confirmed by both the 2001 and 2004 Agreements. (Rakoczy Decl. Ex. D, 2001 Agreement art. 15.5.1(III); Marsden Decl. Ex. A, 2004 Agreement art. 15.5.2).^{2,3}

REDACTED

Accordingly, Sciele admittedly lacks constitutional standing to sue in its own name as the “patentee.” *See* 35 U.S.C. § 100(d); *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1483-84 (Fed. Cir. 1998).

II. Sciele Lacks Standing To Sue In Its Own Name As A Licensee Because Bayer Indisputably Retains Substantial Rights In The '741 Patent Under All Of The Agreements.

The only remaining question is whether Sciele is an exclusive licensee that holds *all*, not just some, substantial rights in the patent. Based on the intent of the parties reflected in all of the agreements cited by Sciele, the answer is unequivocally “no,” which ends the inquiry and requires dismissal for lack of standing. As Sciele freely concedes (*see* Sciele Mem. at 9), “[b]ecause it is undisputed that [Bayer] is the party with legal title to the patent, [Sciele] is entitled to sue in its own name alone, without [Bayer’s] participation, only if [Bayer] has transferred to [Sciele] all substantial rights in the patent.” *Propat Int’l Corp. v. Rpost, Inc.*, 473 F.3d 1187, 1189 (Fed. Cir. 2007); *see also* *Textile Prods.*, 134 F.3d at 1484.

¹ All references to “Sciele Mem.” are to Sciele’s Memorandum Of Law In Opposition To Defendants’ Motion To Dismiss Plaintiffs’ Complaint For Lack Of Standing And Subject Matter Jurisdiction.

² All references to “Rakoczy Decl.” are to the Declaration of William A. Rakoczy, Esq., submitted in connection with Mylan’s Rule 12(b)(1) Motion To Dismiss Plaintiff Sciele’s Complaint For Lack Of Standing And Subject Matter Jurisdiction.

³ All references to “Marsden Decl.” are to the Declaration of William J. Marsden, Jr., Esq., submitted in connection with Sciele’s Opposition To Defendants’ Motion To Dismiss Plaintiffs’ Complaint For Lack Of Standing And Subject Matter Jurisdiction.

Key here is that Sciele must hold *all*, not just some, substantial rights in the patent. As even the authority cited and relied upon by Sciele makes clear, there is no standing if the patentee retains “any substantial right under the patent.” *McNeilab, Inc. v. Scandipharm, Inc.*, 95 F.3d 1164, 1996 WL 431352, at *1-2 (Fed. Cir. July 31, 1996) (unpublished) (“The retention by the patentee of an interest sufficient to support an independent action for damages is the basis of the requirement that the patentee be joined in the suit.”). Even a cursory review of the 2001 and 2004 Agreements, as well as the 2007 Amendment, confirms that Bayer retains substantial rights in the patent,

REDACTED

We briefly address each agreement in turn.

A. Bayer Retains Substantial Rights In The ‘741 Patent Under The Original 2001 Distributorship Agreement.

Sciele casually dismisses the 2001 Agreement as irrelevant and meaningless. The Court should not. The original 2001 Agreement admittedly initiated the parties’ “arrangement” concerning the ‘741 patent

REDACTED

If, as

Sciele repeatedly contends, the intent of the parties governs, then the Court should, and indeed must, consider *all* evidence of such intent, including the initial transfer of rights to the patent reflected in the 2001 Agreement. Sciele effectively concedes that the 2001 Agreement transferred only “certain” rights in the patent, and does not even attempt to argue to the contrary. And for good reason, because

REDACTED

(See Rakoczy Decl. Ex. D, 2001 Agreement art. 3.1). This arrangement made Sciele a bare licensee with no standing to sue, with or without Bayer. See *Textile Prods.*, 134 F.3d at 1484 (“Thus, if a patentee-licensor is free to grant licenses to others,

licensees under that patent are not exclusive licensees.”); *Kalman v. Berlyn Corp.*, 914 F.2d 1473, 1481 (Fed. Cir. 1990) (holding that bare or nonexclusive licensee has no standing under any circumstances, with or without the patentee).

But as even Sciele’s own authority acknowledges, the Court should also “look at what rights have been retained by [Bayer].” *Vaupel Textilmaschinen v. Meccanica Euro Italia*, 944 F.2d 870, 875 (Fed. Cir. 1991). These rights are, to say the very least, substantial, including:

- “[S]ole and exclusive owner[ship]” with the right and obligation to maintain the patent and seek extensions thereof. (*See* Rakoczy Decl. Ex. D, 2001 Agreement art. 15.5.1(III) and 16.4). *See Propat*, 473 F.3d at 1191 (recognizing that responsibility to maintain a patent is “an indication that the party with that obligation has retained an ownership interest in the patent.”).
- The right to develop and introduce new nisoldipine products, and to offer such products to others in certain circumstances. (*See* Rakoczy Decl. Ex. D, 2001 Distributorship Agreement art. 11.1). *See Mentor H/S, Inc. v. Medical Device Alliance*, 240 F.3d 1016, 1018 (Fed. Cir. 2001) (noting that patentee’s ability to develop and manufacture products (for sale only to the licensee) was an indication that the patentee retained a significant ownership interest in the patent).
- The exclusive right to manufacture and supply the patented product to Sciele. (*See* Rakoczy Decl. Ex. D, 2001 Agreement art. 6.2, 7.1). *See Propat*, 473 F.3d at 1191 (finding no transfer of all substantial rights where patentee “retains an economic interest in the patent and a substantial measure of control over decisions affecting the patent rights”).
- The right and sole obligation in the first instance to “***promptly take such appropriate steps as are determined by BAYER to be necessary in order to protect the interests of the PARTIES . . .***” which steps “***are reserved exclusively for the decision of BAYER . . .***” (Rakoczy Decl. Ex. D, 2001 Agreement art. 16.2 (emphasis added)). *See Mentor*, 240 F.3d at 1018 (“[I]n light of [the patentee’s] substantial retained rights, particularly its initial right and obligation to sue for infringement, we conclude that [the licensee] did not receive all substantial rights in the patent.”).

The intent of the 2001 Agreement is clear. While Bayer could have relinquished all substantial rights in the patent, it didn’t, but rather intentionally retained a bundle of substantial rights. Nothing in the 2001 Agreement even came close to effecting a transfer that would confer

standing to sue on Sciele. Contrary to Sciele's assertions, as discussed below, the "arrangement" initiated with the 2001 Agreement was merely "continue[d]" in the 2004 Agreement, which did not materially change or diminish Bayer's substantial retained rights in the patent.

B. Bayer Retains Substantial Rights In The '741 Patent Under The New 2004 Distributorship Agreement — Essentially The Same Rights That Bayer Retained In The Prior 2001 Agreement.

Sciele now suggests that the 2004 Agreement somehow changed the world and rendered Bayer's retained rights "insubstantial." (*See* Sciele Mem. at 11).⁴ Not true. In fact, to the extent the 2004 Agreement did anything, **REDACTED**

and confirms that Bayer retained substantial rights in the patent, and that there was no intent to effectuate a transfer of all rights to Sciele. Sciele therefore lacks standing to sue under the 2004 Agreement as well.

1. Sciele Remains A Bare Licensee Under The 2004 Agreement, With No Standing To Sue With Or Without Bayer.

To begin with,

REDACTED

REDACTED

Quite the contrary,

(*See* Marsden Decl. Ex. A, 2004 Agreement art. 2.2).

REDACTED

(*See id.* at 1)

REDACTED

In addition, as with the 2001 Agreement,

REDACTED

⁴ The 2004 Agreement and 2007 Amendment, which Sciele filed under seal, were not available to Mylan before Sciele filed its response.

REDACTED

(See *id.* art. 3.1)

REDACTED

REDACTED

namely, that Sciele would *not* receive an exclusive license to all of the material patent rights.

REDACTED

These, of course, are the rights of a bare licensee with no standing to sue, with or without Bayer. See *Textile Prods.*, 134 F.3d at 1484; *Kalman*, 914 F.2d at 1481.

2. Bayer Retains Substantially The Same Rights Under The 2004 Agreement As It Did Under The Prior 2001 Agreement.

The 2004 Agreement also confirms that Bayer retained substantial rights in the ‘741 patent that did not materially change from the 2001 Agreement. Indeed, the 2004 Agreement did not diminish any of Bayer’s retained rights.

First, the 2004 Agreement, like the 2001 Agreement,

REDACTED

(See

Marsden Decl. Ex. A, 2004 Agreement art. 15.5.2 (“BAYER is and shall be . . . the sole and exclusive owner of the [‘741 patent] . . .”). While Sciele dismisses this factor out of hand (see Sciele Mem. at 15), Sciele nonetheless concedes that it is an important factor that the Court must consider in its analysis. See *Mentor*, 240 F.3d at 1018.⁵ This is especially true here, where in the over 6 years since executing the original 2001 Agreement, Bayer could have, *but expressly did not*, transfer actual legal title and ownership of the patent.

REDACTED

⁵ Sciele also makes the odd comment that somehow exclusive licensees sue alone “all the time” without the patentee, though it conspicuously omits any evidence or authority for such filings, and certainly not in a Hatch-Waxman setting where the 30-month stay is at issue. (See Sciele Mem. at 15).

REDACTED

— thus evidencing a clear intent to retain a substantial interest in the patent.

Along similar lines,

REDACTED

(See Marsden Decl. Ex. A, 2004 Agreement art. 16.6). Here again, the Federal Circuit has recognized that the responsibility to maintain a patent is “an indication that the party with that obligation has retained an ownership interest in the patent.” *Propat*, 473 F.3d at 1191; *see also Mentor*, 240 F.3d at 1018. And here again,

REDACTED

Second, as with the 2001 Agreement,

REDACTED

Agreement art. 11.1

(See Marsden Decl. Ex. A, 2004

REDACTED

Agreement,

REDACTED

(See *id.*). So just like the 2001

This, too, is an indication that Bayer has retained significant ownership rights in the ‘741 patent under the 2004 Agreement as well. *See Mentor*, 240 F.3d at 1018 (noting that patentee’s ability to develop and manufacture products (for sale only to the licensee) was an indication that the patentee retained a significant ownership interest in the patent).

REDACTED

(*See* Sciele Mem. at 15-16). Wrong

again.

REDACTED

Third, and as already noted above, under the 2004 Agreement,

REDACTED

(*See, e.g.*, Marsden Decl. Ex. A, 2004 Agreement art. 2.2

REDACTED

Under the 2004 Agreement,

REDACTED

(*See id.* art. 16.1). In the 2004 Agreement, Bayer therefore continues to “retain an economic interest in the patent and a substantial measure of control over decisions affecting patent rights.” *See Propat*, 473 F.3d at 1191.

Fourth, and perhaps most importantly,

REDACTED

(See Marsden Decl. Ex. A, 2004 Agreement art. 16.2 (emphasis added)).

REDACTED

(*Id.* (emphasis added)).

REDACTED

Again, these are precisely the same enforcement rights that Bayer retained under the 2001 Agreement.

All told, Bayer retained the very same substantial rights in the patent under the 2004 Agreement, as it did under the 2001 Agreement:

<u>Patent rights</u>	<u>Party that was granted and/or retained patent right under 2001 Distributorship Agreement</u>	REDACTED
Sole and exclusive ownership of patent	Bayer	REDACTED
Right and obligation to maintain the patent, and to seek extensions thereof	Bayer	REDACTED
Right to develop and introduce new nisoldipine products in certain circumstances	Bayer	REDACTED
Exclusive right to manufacture the patented product	Bayer	REDACTED
Right and obligation to sue potential infringers in the first instance	Bayer	REDACTED

Contrary to Sciele's assertions, nothing in the 2004 Agreement altered or diminished Bayer's substantial rights in the patent. All told, these are precisely the circumstances that the Federal Circuit has held do not evidence a transfer of all substantial rights in the patent. In *Mentor*, for example, as in this case, the patentee retained the right to manufacture the product and to develop other products under the patent (for sale to the licensee);

the patentee was obliged to maintain the patent; and the patentee had the first right and obligation to sue parties for infringement. *See Mentor*, 240 F.3d at 1018. The Federal Circuit concluded that “in light of [the patentee’s] substantial retained rights, particularly its initial right and obligation to sue for infringement, we conclude that [the licensee] did not receive all substantial rights in the patent.” *Id.* ; *see also Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 917 F. Supp. 305, 307-11 (D. Del. 1995) (dismissing exclusive licensee’s patent infringement counterclaim for lack of standing for failure to include actual patent owner); *Monsanto Co. v. Aventis Cropscience SA*, 226 F. Supp. 2d 531, 539-40 (D. Del. 2002) (partially dismissing action for lack of standing because licensees did not own “all substantial rights” in the patent). The Court should, and indeed must, reach the same conclusion here. The Court should also reject Sciele’s unfounded assertion that Mylan’s motion is based on “outdated” information where, as here, Bayer retained the same substantial rights in the patent under both the 2001 and 2004 Agreements.

REDACTED

3.

REDACTED

REDACTED

(*See Sciele Mem.* at 12). This selective, and indeed disingenuous, reading of the 2004 Agreement is complete nonsense.

REDACTED

REDACTED

REDACTED

(See Marsden Decl. Ex. A, 2004 Agreement art. 16.2 (emphasis added)).

REDACTED

To repeat, this is an express command and contractual obligation:

REDACTED

REDACTED

REDACTED

REDACTED

Wrong again.

REDACTED

See Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1131 (Fed. Cir. 1995) (purpose of requiring licensee to sue with patent owner is “to enable the alleged infringer to respond in one action to all claims of infringement for his act, and thus either to defeat all claims in one action, or by satisfying one adverse decree to bar all subsequent actions.” (quoting *Indep. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459 (1926))).

REDACTED

See McNeilab, 1996 WL 43152, at *1-2 (“The retention by the patentee of an interest sufficient to support an independent action for damages is the basis of the requirement that the patentee be joined in the suit.”).

The cases on which Sciele relies do not hold to the contrary. In *Vaupel*, 944 F.2d at 870, for example, the “dispositive” factor was an agreement that granted the licensee the “sole right to sue for all infringements.” *Id.* at 875-76 (holding that grant of sole right to sue was

“particularly dispositive”). That, of course, is not the case here — far from it in fact.

REDACTED

Likewise, in *Speedplay Inc. v. Bebop, Inc.*, 211 F.3d 1245 (Fed. Cir. 2000), the relevant agreement granted the licensee the “sole right to enforce the Licensed Patents.” *Id.* at 1251.

Again, not so here,

REDACTED

Moreover, the right to sublicense in *Speedplay* was irrelevant where the licensee possessed the sole right to sue and enforce the patent.

REDACTED

⁶ Under controlling authority and the undisputed evidence of record, the 2004 Agreement fails as a matter of law to confer the necessary standing to sue on Sciele.

C. Nothing In The 2007 Amendment Eliminates Or Diminishes Bayer’s Substantial Rights In The Patent, Or Otherwise Grants Sciele All Substantial Rights Necessary For Standing.

To top it off,

REDACTED

is an outright admission that the 2004 Agreement failed to provide Sciele with all substantial rights in the patent. Contrary to Sciele’s assertions, the 2007 Amendment itself does nothing to remedy that problem.

REDACTED

⁶ Also inapposite is *McNeilab, Inc. v. Scandipharm, Inc.*, 95 F.3d 1164, 1996 WL 43152 (Fed. Cir. July 31, 1996) (unpublished), where the license actually negated any obligation of the patent owner to sue infringers. *See id.* at *4-5. And in *Gould v. Control Laser Corp.*, 462 F. Supp. 685 (M.D.Fla. 1978), unlike here, the patentee transferred every single right in the patent, except for the right to half the royalties and a limited veto over certain agreements. *See id.* at 687.

REDACTED

(*See* Marsden Decl. Ex. B, 2007

Amendment art. 3).

REDACTED

REDACTED

(*cf.* Marsden Decl. Ex.

A, 2004 Agreement art. 16.3 *with* Ex. B, 2007 Amendment art. 2.9).

REDACTED

(*See* Marsden Decl.

Ex. B, 2007 Amendment art. 2.9)

REDACTED

In the end, in at least three separate agreements, Sciele had multiple opportunities to acquire ownership of, and/or all substantial rights in, the patent. It didn't. Rather, in each case, as reflected by the clear and unambiguous intent of the parties, Bayer retained substantial rights in the patent—rights that cannot be disregarded or ignored for standing purposes,

REDACTED

Sciele therefore lacks the necessary standing to sue, thus requiring dismissal of the Complaint for lack of subject matter jurisdiction.

III. The Court Should Deny Sciele's Request For Leave To Amend To Join Bayer.

Realizing that it lacks the necessary standing, Sciele alternatively requests leave to file an amended complaint to add Bayer, which has not to date sued. The Court should deny that request on several grounds and dismiss the case, leaving Bayer free to file its own suit (with or without Sciele) if it so chooses.

First of all, Sciele admittedly lacks standing to sue on its own. As Sciele acknowledges, the general rule in these circumstances requires dismissal. *See Textile Prods.*, 134 F.3d at 1485 (affirming district court's dismissal of the plaintiff's patent infringement claims where the plaintiff was an exclusive licensee, but not an assignee, of the patent-in-suit); *Prima Tek II v. A-Roo Co.*, 222 F.3d 1372, 1382 (Fed. Cir. 2001) (dismissing an action brought by an exclusive licensee due to its failure to join the patent owner); *Procter & Gamble Co.*, 917 F. Supp. at 307-11 (dismissing exclusive licensee's patent infringement counterclaim for lack of standing for failure to include actual patent owner); *Monsanto Co.*, 226 F. Supp. 2d at 541 (partially dismissing action for lack of standing because licensees did not own "all substantial rights" in the patent). Sciele has provided no justification, much less a legitimate one, for departing from that rule now, especially when Sciele jumped the gun and secured a 30-month stay to which it is not entitled, as discussed below. The Court is well within its discretion to dismiss.⁷

⁷ *Schreiber Foods, Inc. v. Beatrice Cheese, Inc.*, 402 F.3d 1198, 1203 (Fed. Cir. 2005), does not hold otherwise. The issue before the court there was "whether a judgment is void when there is a temporary transfer of the patent in suit to a non-party, which temporarily deprives the court of jurisdiction, even though the plaintiff owned the patent at the commencement of the suit and at the time of judgment?" *Id.* Here, Sciele does not own the '741 patent and, hence, *Schreiber* is uninformative for present purposes.

Second, “[t]he question of standing to sue is a jurisdictional one[.]” *Rite-Hite Corp. v. Kelly Co.*, 56 F.3d 1538, 1551 (Fed. Cir. 1995). Standing is a “threshold question in every federal case, determining the power of the court to entertain the suit.” *Warth v. Seldin*, 422 U.S. 490, 498 (1975). “Federal courts are under an independent obligation to examine their own jurisdiction, and standing ‘is perhaps the most important of [the jurisdictional] doctrines.’ ” *Monsanto Co.*, 226 F. Supp. 2d at 537 (quoting *FW/PBS Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990)). Whether the jurisdictional infirmity is constitutional or, as Sciele argues, prudential, the Court should not proceed in the absence of proper standing and jurisdiction. The safest, and most prudent, course in these circumstances would be to dismiss, rather than act in the absence of jurisdiction. *See, e.g., Vennen v. Sweet*, 758 F.2d 117, 123 (3d Cir. 1985) (court noting that “if we have no jurisdiction, we cannot act”).

Third, and perhaps most importantly, leave to amend will cause enormous prejudice to Mylan, while harming Sciele not in the least. Courts do not grant leave to amend, or allow joinder for that matter, where such an amendment would unduly prejudice the opposing party. *See Winer Family Trust v. Queen*, 503 F.3d 319, 331 (3d Cir. 2007). Indeed, a key factor in the Federal Circuit’s decision in *Prima Tek II* that warranted dismissal over amendment or joinder was possible prejudice to the defendant. 222 F.3d at 1382. The overwhelming prejudice to Mylan warrants dismissal here as well.

This is no ordinary patent case. As explained in Mylan’s opening brief, this case arises under the Hatch-Waxman Amendments, which Congress enacted for the express purpose of “get[ting] generic drugs into the hands of patients at reasonable prices — fast.” *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). To achieve that goal, Hatch-Waxman created the ANDA procedure and “a mechanism to facilitate the adjudication of claims of infringement of

patents relating to the innovator's drugs" before the generic drug has been marketed. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003). As part of that procedure, if the patentee files a suit for infringement within 45 days of receiving notice of the ANDA and paragraph IV certification, FDA approval of the ANDA is automatically stayed — regardless of the suit's merit or lack thereof — for 30 months. *See* 21 U.S.C. § 355(j)(5)(B)(iii). This so-called 30-month stay is akin to a preliminary injunction against Mylan, which is imposed without any showing of likelihood of success on the merits just for properly filing a suit within the 45-day period.

In this case, however, Sciele has manipulated the system by prematurely filing this suit and obtaining a 30-month stay to which it is not lawfully entitled. The true patentee, Bayer, did not sue Mylan within the 45-day period for obtaining such a stay, and indeed has never sued Mylan at all. Instead, Sciele jumped the gun alone and filed this suit without the requisite standing. By doing so, Sciele obtained a 30-month stay of approval to which it was not entitled. Sciele now wants the Court to effectively condone its premature filing by joining Bayer, even though Bayer never sued within the 45-day period and is not entitled to the stay. Allowing the amendment will effectively grant a stay to Sciele, which was never entitled to file this suit in the first place, as well as to Bayer, which admittedly never filed within the 45-day period. The prejudice to Mylan is manifest — it is laboring under a 30-month stay from a lawsuit that was improperly filed without standing.

In contrast, the only prejudice to Sciele is the dismissal of a suit it should not have brought in the first instance, at least not without Bayer. That goes double for Bayer, which admittedly did not sue within the 45-day period and is not entitled to a stay under any circumstances, and indeed has not sued to date. It also bears emphasizing that neither Sciele nor

Bayer are left without a remedy. If they still want to sue, they can still do so, provided Bayer is a plaintiff, and try to prove up their case. But Bayer should not be permitted to jump in now to save Sciele's premature attempt to salvage the 30-month stay that neither one of them is entitled to. Indeed, Sciele puts the cart before the horse in arguing for joinder and leave to amend. If it had no right to sue alone and obtain a 30-month stay in the first place, it should not be permitted to fix and cure that problem by adding Bayer—not where it would so prejudice Mylan. Nor can Sciele legitimately complain about losing a 30-month stay that it was never entitled to. Indeed, if Sciele was so concerned about the stay, it should have sued with Bayer in the first place. The fact is, Mylan will suffer enormous prejudice if forced to proceed under the yoke of an improper 30-month stay. That is reason enough to deny leave to amend and/or joinder.

Sciele's reliance on *Intellectual Prop. Development v. TCI Cablevision of California*, 248 F.3d 1333 (Fed. Cir. 2001) ("IPD") and *Abbott Labs.*, 47 F.3d at 1128 is misplaced.⁸ There is no argument in either case that permitting amendment of the complaint to add the patentee would result in undue prejudice to the opposing party. Here, as stated above, Mylan would be severely and irreparably prejudiced by having been kept off the market due to the implementation of an unlawfully obtained 30-month stay obtained via the commencement of premature litigation by a party lacking standing to sue in its own name.

Accordingly, dismissal is the only appropriate remedy here because of the undue prejudice that Mylan is already suffering, and will continue to suffer, as a result of Sciele's premature and improper suit. *See, e.g., Prima Tek II*, 222 F.3d at 1382 (dismissing exclusive licensee's suit due to failure to join patent owner); *Int'l Gameco v. Multimedia Games*, 504 F.3d

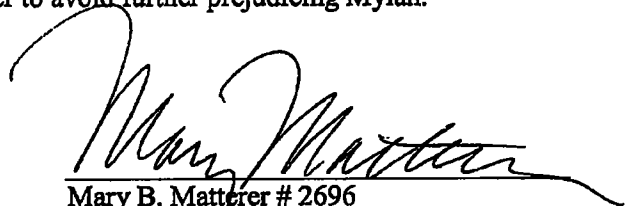
⁸ In both of these cases, it should be noted, the courts concluded that the plaintiff was an exclusive licensee with less than all substantial rights in the patents in suit and, therefore, lacked standing to sue on its own without joining the patent owner.

1273, 1280 (Fed. Cir. 2007) (dismissing exclusive licensee's suit due to failure to join patent owner); *Procter & Gamble Co.*, 917 F. Supp. at 307-11 (dismissing exclusive licensee's patent infringement counterclaim for lack of standing for failure to include actual patent owner); *Monsanto Co.*, 226 F. Supp. 2d at 541 (partially dismissing action for lack of standing because licensees did not own "all substantial rights" in the patent).

CONCLUSION

Sciele neither holds legal title to, nor all substantial rights in, the '741 patent. Sciele therefore lacks standing to sue in its own name. The Court therefore should dismiss Sciele's Complaint for lack of standing and subject matter jurisdiction. The Court should also deny Sciele's request for leave to amend in order to avoid further prejudicing Mylan.

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